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| EXAMINER | |
|---|---|
| ROANE, AARON F | |

| ART UNIT | PAPER NUMBER |
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| 3769 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/727,096 | SWANSON, DAVID K. | |
| | Examiner | Art Unit | |
| | AARON ROANE | 3769 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *7,10-12,28-35,37-40,46 and 54-59* is/are pending in the application.

4a) Of the above claim(s) *12 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,10,11,28,30-35,37-40,46 and 54-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 10, 11, 28, 30-33, 37-40, 43, 46 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (U.S. Patent 6,185,442) in view of Geeham (U.S. Patent 5,295,481) in further view of Lundback (U.S. Patent 4,736,749) in still further view of Ostroff et al. (U.S. Patent 7,149,575).

Regarding claims 7, 11, 28, 30, 40 and 43, Samson discloses a flexible tube (flexible tube 15) defining a central axis and having a proximal end and a distal end through which suction is supplied; a flexible suction device ("suction cup" 10 which is formed from a flexible material since it has a resilient wall 12), the suction device being connected to and coaxial with a distal end of a flexible electrical tube (portion 17) and having a flexible distal portion that includes a peripheral sealing surface (13) having a shape and a size for being removably securable to myocardial tissue, the suction device extending from the flexible electrical tube distal end such that the peripheral sealing surface is located distally of the flexible electrical tube distal end and extends outwardly beyond an outer surface of the flexible electrical tube distal end such that suction device across the

peripheral sealing surface is wider than the flexible electrical tube distal end; and a tissue electrode ("electrode" 16) that is too small to form a transmural lesion in myocardial tissue; wherein the suction device does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue, see col. 3:36-col.4:57 and figures 1-7, particularly figures 1 and 3. Samson fails to disclose the peripheral sealing surface of the suction device is flexible and the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device, such that the tissue stimulation element is not located within an inner space defined by the suction device, wherein the tissue stimulation element is a discrete tissue stimulation element that does not extend around the peripheral sealing surface. Samson also fails to disclose the tissue electrode is a tissue stimulation element/electrode and a source of stimulation energy operably connected to the stimulation element/electrode. Although Samson discloses the electrode (stimulation element) is used for electrical sensing, see col. 3:36-61, Samson fails to disclose the stimulation element is used for both electrically stimulating and electrically sensing. Samson fails to disclose the signal line extending from the tissue stimulation element goes into and through the flexible suction tube for connection to a source of stimulation energy. Additionally, Samson fails to disclose the suction device is coaxial with a distal end of the flexible tube, wherein the examiner has interpreted coaxial to mean alignment and overlapping of central longitudinal axis. Geeham discloses a suction device having a plurality of tissue contacting electrodes (32) and teach "defibrillation is provided by electrical contact between the patient's chest and two or more electrodes 32 located at the peripheral rim 30, and connected thereto by any practical means known in

the art. As an example shown in FIGS. 3 and 4, the electrodes 32 may be U-shaped so as to fold around the peripheral rim 30 and then bolt to the suction cup member 20 via bolts 32'. In the examples shown in the Drawing, two pairs of electrodes 32a, 32b, and 32c, 33d are provided. The first set of electrodes 32a, 32b are connected to a low voltage circuit $C_1$, have opposite polarity and are located at opposite positions on the peripheral rim 30. The second set of electrodes 32c, 3d are connected to a high voltage circuit $C_2$, have opposite polarity and are located at opposite positions on the peripheral rim 30. Other electrode configurations are possible, and it is preferred for each set of electrodes to be well separated from any other set of electrodes. The upper end 16a of the column member 16 is provided with switches 34 and 36 which respectively control the low and high voltage circuits. These switches may be momentary (preferred for the high voltage circuit), or non-momentary (preferred for the low voltage circuit) on-off type switches, and they may be further associated with CPR assist device circuitry which provides periodic pretimed shocks of electricity to the electrodes, predetermined or user controlled levels of current, voltage and power to the electrodes. A transformer T provides a boost or reduction in the voltage, a transformer being optionally in either or broth, the high and low voltage circuits," see col. 3:27-58 and figures 1-4. Lundback discloses a surgical apparatus comprising an elongate flexible tube (8); a cup-shaped suction device (1-3 collectively) associated with the distal region of the tube, wherein the cup-shaped suction device is made from a flexible material (flexible bending portions of 2), a tissue electrode (the tissue contacting side of 30) on the suction device distal surface, see col. 3 and 4 and figures 1-4. Lundback teaches that the device is used as a diagnostic device or a

therapeutic device, where the "diagnostic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, for example, electrodes for electroencephalography (ECG), electrodes for electromyography (EMG), sensors for skin temperature, humidity, and pH, biosensors and other sensors for indirect or direct measurement of blood gases, intramuscular sensor probes for, e.g., measurement of local peripheral circulation by laser-Doppler techniques, microphones for the registration of heart sounds, optical conductors for observation of the skin, etc. Therapeutic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, e.g., electrodes for electrical stimulation of muscles, defibrillators, injectors for intramuscular administration of pharmaceuticals, electrodes for hyperthermal treatment, devices for percutaneous administration of pharmaceuticals, etc." It is extremely well known in the art to provide electrodes with both electrical sensing capability and electrical pacing/stimulation capability. Lundback also teaches disposing the signal conductor line bundle 7 within the lumen of the vacuum tube of suction tube as an alternate/equivalent means of connecting the electrode element to a energy source and/or signal monitor, see col. 4:51-61 and figures 1-3. Ostroff et al. disclose a electrical cardiac device/system and method and teach providing the electrode(s) with both stimulation (pacing) and sensing capability in order to provide an enhanced device/treatment wherein one or more electrodes provide both stimulating and sensing in order to treat the patient, see col. 10:24-59 and figure 15D. Finally, although Sampson discloses an electrical flexible tube (17) and a flexible suction tube (15) having their distal ends connected to the suction device, it is the flexible electrical tube (17) that is coaxially connected to the suction

device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange the connecting points of the distal ends of the flexible suction tube (15) and the flexible electrical tube (17) such that the flexible suction tube and the suction device are coaxial, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Samson, as taught by Geeham, to provide the suction device with an alternate/equivalent embodiment where electrodes that are placed on a flexible peripheral distal surface of the suction cup and do not extend completely around the peripheral sealing surface in order to provide an improved electrical connection and conduction between the tissue and the electrode, and as further taught by Lundback, to provide the suction cup device with alternate use as a therapeutic device and using the electrode as a stimulation electrode, instead being used a diagnostic device using the electrode as a sensing electrode, and operably connecting the stimulation electrode to a source of stimulation energy, and also taught by Lundback, to disposing the signal conductor line bundle 7 within the lumen of the vacuum tube of suction tube 8 as an alternate/equivalent means of connecting the electrode element to a energy source and/or signal monitor, and as still further taught by Ostroff et al., to provide the electrode(s) with both stimulation (pacing) and sensing capability in order to provide an enhanced device/treatment wherein one or more electrodes provide both stimulating and sensing in order to treat the patient, and as finally taught, to rearrange the connecting points of the distal ends of the flexible suction tube (15) and the flexible electrical tube (17) such that

the flexible suction tube and the suction device are coaxial, since it has been held that rearranging parts of an invention involves only routine skill in the art.

Regarding claims 10 and 46, Samson discloses the suction device is substantially cup-shaped (10), see figures 1 and 3.

Regarding claims 31-33 and 37-39, Samson in view of Geeham in further view of Lundback disclose the claimed invention except for the stimulation element defining a perimeter of about 1.5 mm to 3 mm, a thickness of about 0.01 mm and a diameter of about 0.5 mm to 1.0 mm. The examiner takes official notice of the perimeter as it is trivial to provide the electrically conductive members, i.e. the electrodes of Geeham with perimeter of about 1.5 mm to 3 mm corresponding to the cross-sectional area of wires (W, see col. 3:65 – col. 4:18 and figure 4) and a thickness of about 0.01 mm in order to electrode with its fully functioning capabilities. It should be further noted that a circular perimeter of 1.5 mm to 3 mm yields a diameter of about 0.5 mm to 1 mm. As Applicant has traversed the official notice rejection, the examiner now provides a prior art reference which has been cited only to support the previous official notice rejection (see MPEP 2144.03(a-d), particularly 2144.03(d)). Specifically it is the cross-section of the electrode that is relevant for this rejection. Ostroff et al. disclose an electrical tissue stimulating device and provide an electrode having a circular cross-section with diameter of 1-5 mm, see col. 5:351-67 and figure 1. Since the perimeter, **P**, of the electrode cross-section is given by

$$\mathbf{P} = 2 * \pi * \mathbf{r} = \pi * \mathbf{D},$$

where **D** is the diameter and **r** is the radius. Therefore, in order for the perimeter, P, to be about 1.5 mm to 3 mm, the diameter, **D**, must be about 0.47mm to 0.95mm. Since 1mm is about 0.95mm (a difference of less than 5.3%), the perimeter and diameter recitations have been met. Regarding the thickness of about 0.01mm, it can easily be seen from the **figure A** below, given a circular cross-section, a thickness can be defined which the circular cross-section inherently has and that is about 0.01mm. Figure A depicts the electrode's circular cross-section having a diameter, D and thickness, T. It should be noted that thickness of 0.01mm is located almost at the top of the cross-section and for further illustration it should be noted the distance from the center of the circular cross-section to where the thickness is 0.01mm is equal to the square root of $(0.5\text{mm})^2$ minus $(0.005\text{mm})^2$.

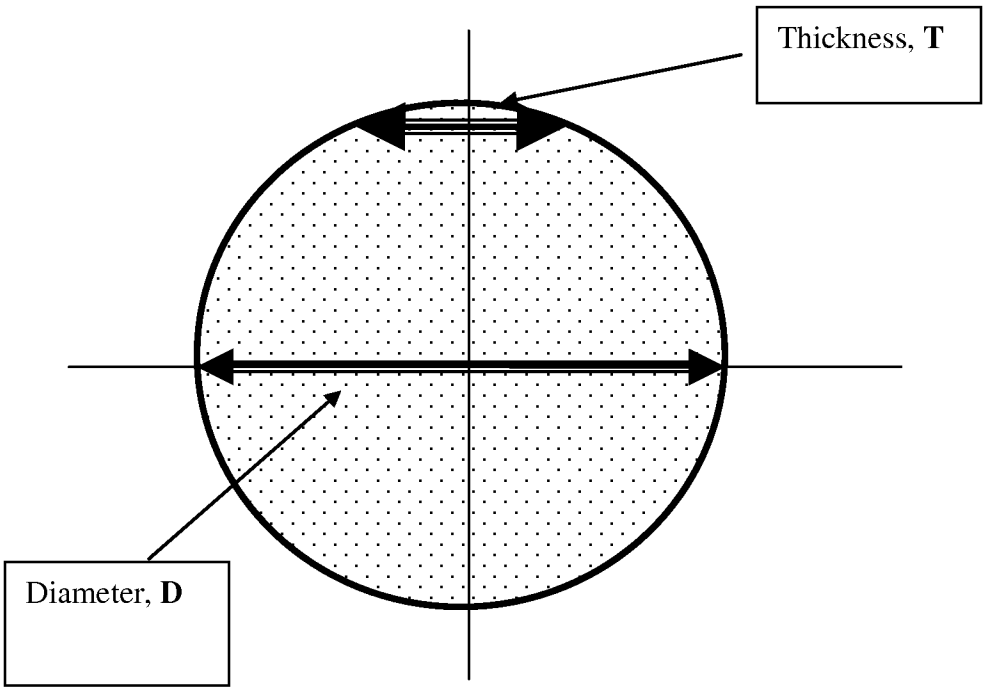


**Figure A**

Finally, Applicant may argue Geeham doesn't disclose a circular cross-section. The examiner counters with the fact that a portion of the cross-section is circular (the upper portion) and it is that portion that defines (in view of the official notice and Ostroff et al. (U.S. Patent 7,149,575)) the recited dimensions.

Regarding claims 54-56, Samson in view of Geeham in further view of Lundback in still further view of Ostroff et al. disclose the claimed invention, see in particular the electrodes 32a-32d and corresponding wires W) of Geeham in figure 4.

Regarding claims 57-59, Samson in view of Geeham in further view of Lundback disclose the claimed invention in still further view of Ostroff et al., see in particular the sealing surface of Geeham in figure 4.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (U.S. Patent 6,185,442) in view of Geeham (U.S. Patent 5,295,481) in further view of Lundback (U.S. Patent 4,736,749) in still further view of Ostroff et al. (U.S. Patent 7,149,575) as applied to claim 28 above, and finally in view of Colliou et al. (U.S. Patent 7,020,531).

Regarding claims 34 and 35, Samson in view of Geeham in further view of Lundback in still further view of Ostroff et al. disclose the claimed invention except for explicitly reciting that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10 mA and two stimulation pulses per second. Colliou et al. disclose a stimulating suction electrode device and teach providing the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μsec to 20 msec in order to provide electrical stimulation, see col. 23, line 46 through col. 24, line 6 and figures 16A and 16B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Samson in view of Geeham in further view of Lundback in still further view of Ostroff et al., as taught by Colliou et al., to provide the device with a power source capable of delivering 1 mA to 30 mA of current,

a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 μsec to 20 msec in order to provide electrical stimulation to tissue.

## Response to Arguments

Applicant's arguments filed 12/29/2010 have been fully considered but they are not persuasive.

Applicant's arguments are unpersuasive and will be addressed in turn.

First on page 8, last paragraph through page 10, 3rd paragraph, Applicant argues that none of the references alone or together disclose a suction device having a size and shape for being removably securable to myocardial tissue. It is argued that the prior art disclose suction cups/devices that are too large for such a function.

This particular recitation is a recitation of a functional limitation. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for

performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). Presently, the prior art of record, separately and in combination can perform the function of being removably secured to myocardial tissue. Additionally, the size of a fetus' cranium and the size of an adult heart are comparable, which further lends as evidence against Applicant's argument.

Regarding Applicant's argument on page 10, last paragraph, the argument/remark is unpersuasive as it presumes some damage threshold. This presumption is something which the examiner can not and should not be in agreement with. There is nothing in the claim language which places a minimum threshold on the stimulation energy, power, densities thereof and the like. Additionally, Lundback et al. teach the use of the electrode for sensing and stimulating and therefore no function of the primary reference is destroyed.

Regarding the arguments/remarks of page 11, they are directed to a recitation of 1) intended use, 2) language directed to how the device/element is intended to be employed and/or 3) a functional limitation. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the

claim. A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987). It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971).

**The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.**

**This action is made FINAL.**

## Conclusion

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769